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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/981,900	10/18/2001	Masomch B. Sticklen	MSU 4.1-539	9143
21036	7590	08/12/2004	EXAMINER	
MCLEOD & MOYNE, P.C. 2190 COMMONS PARKWAY OKEMOS, MI 48864			KALLIS, RUSSELL	
			ART UNIT	PAPER NUMBER
			1638	
DATE MAILED: 08/12/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

<p align="center">Office Action Summary</p>	Application No. 09/981,900	Applicant(s) STICKLEN ET AL.	
	Examiner Russell Kallis	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 May 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15,17-61,63-79 and 81-104 is/are pending in the application.
- 4a) Of the above claim(s) 18-46,83-99,101 and 104 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15,17,47-61,63-79,81,82,100,102 and 103 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 May 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____. | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
6) <input type="checkbox"/> Other: _____. |
|---|--|

DETAILED ACTION

Claims 1-15, 17-61, 63-79 and 81-104 are pending. Claims 16, 62 and 80 have been cancelled. Claims 18-46, 83-99, 101 and 104 are withdrawn. Claims 1-15, 17, 47-61, 63-79, 81-82, 100, 102 and 103 are examined.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

Claims 1-15, 17, 47-61, 63-79, 81-82, 100, 102 and 103 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is maintained for the reasons of record set forth in the Official action mailed 2/18/2004. Applicant's arguments filed 5/20/2004 have been considered but are not deemed persuasive.

Applicant interprets M.P.E.P. 2163, "a representative number of species", by stating "the species which are adequately described are representative of the entire genus" and continues by asserting "when there is little variation within the genus, one must describe a sufficient variety to reflect the variety within the genus". This statement ignores the population requirement of M.P.E.P. 2163 i.e. "a representative number" because one would not know whether there was little variation between species within a genus unless an adequate number of them were described and shown to have little or no variation.

Further, Applicant asserts that there is a high degree of homology (68.5%) between the ligninases taught in the specification (see page 38 line 2) and since a substantial degree of variation does not exist, the ligninases disclosed in the specification provide adequate written description for the claimed genus of ligninases (response page 38 lines 12-16). The ligninases Applicant refers to on page 37 (SEQ ID NO: 11 and 13) are both from *Phanerochaete chrysosporium* and hence constitute a small sample size of the variation among the species of microorganisms that have ligninases. Further, Applicant's assertion on page 38, line 2, that 68.5 % homology is a very high percentage of homology is not consistent with levels of high percentage homology accepted in the art.

Furthermore, Applicant asserts that amended claims 1, 47 and 65 are drawn to a genus of cellulases and have met the written description requirement by disclosing an enzymatic function and the chemical structure set out in the sequences (response page 39 lines 7-11; see also pages 35-37). Applicant has not described a common structure function relationship for the four claimed enzymes i.e. a common enzymatic function and a common chemical structure set out in the sequences. Applicant has only described that they act to break down different parts of cellulose releasing different products and provided one DNA sequence for each of the four distinct enzymes of an endoglucanase, an exoglucanase, a dextranase and a beta-glucosidase.

The Federal Circuit has recently clarified the application of the written description requirement to inventions in the field of biotechnology. The court stated that, "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial

portion of the genus.” *See University of California v. Eli Lilly and Co.*, 119 F.3d 1559; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997).

Claims 1-15, 17, 47-61, 63-79, 81-82, 100, 102 and 103 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a transformed herbaceous plant comprising a DNA encoding a cellulase and a lignase operably linked to a plastid targeting DNA, does not reasonably provide enablement for a woody plant so transformed or for a transformed plant comprising a DNA encoding a cellulase and a ligninase operably linked to a DNA for targeting to any organelle. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. This rejection is maintained for the reasons of record set forth in the Official action mailed 2/18/2004. Applicant’s arguments filed 5/20/2004 have been considered but are not deemed persuasive.

Applicant asserts that the amendments to the claims have overcome the unpredictability and of transforming a plant with DNA encoding a cellulase and a ligninase and expressing the enzymes in the plant (response pages 40, lines 16-29). Applicant has not addressed the arguments with respect to the DNA sequences in the previous Office Action of 2/18/2004 that undue trial and error experimentation would be needed by one skilled in the art to make and clone a multitude of non-exemplified cellulase and ligninase encoding DNA sequences and would require one of skill in the art to test in a myriad of non-exemplified plants for lignocellulose degradation in a multitude of non-exemplified transformed plant species.

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Claim Rejections - 35 USC § 103

Claims 1-15, 17, 47-61, 63-79, 81-82, 100, 102 and 103 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Himmel M. *et al.* U.S. Patent 6,013,860 issued January 11, 2000, in view of Crawford *et al.*, U.S. Patent 5,200,338 issued April 6, 1993; and in further view of de Boer, H. *et al.* Gene, 1987, Vol. 60; pages 93-102 and Applicants admissions. This rejection is maintained for the reasons of record set forth in the Official action mailed 2/18/2004. Applicant's arguments filed 5/20/2004 have been considered but are not deemed persuasive.

Applicant asserts that none of the prior art references in alone or in combination show or suggest all of the claim limitations and that there is no suggestion or motivation to combine the reference teachings (response page 43 lines 7-14). Applicant is invited to point out which limitations were not included in the rejection. Applicant does not teach any unexpected results that would support the argument that it was not obvious to combine the references.

No claim is allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Russell Kallis whose telephone number is (571) 272-0798. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (571) 272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Russell Kallis Ph.D.
August 4, 2004



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